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09/912,697	07/25/2001	Nicholas C. Nicolaides	MOR-0040	5193

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/912,697	NICOLAIDES ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,14-25,27,38 and 42-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,14-25,27,38 and 42-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1-6-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 3 14-25, 27, 38, and 42-50 are pending and under consideration in the application.

2. In the prior action, the Final Action mailed on July 7, 2004, claims 1, 3, 14-25, 27, 38, and 42 were rejected. In the Response accompanying the RCE filed on January 6, 2005, the Applicant amended claim 3, and added new claims 43-50.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on January 6, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **(New Rejection)** Claims 1, 14-25, 27, 38, 43, and 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. These claims read on two genera of inventions. First, the claims read on genus of methods of making antibiotic resistant bacteria through introducing into the bacteria a dominant negative allele of a mismatch repair gene. Second, the claims read on a genus of antibacterial resistant bacteria produced by such methods and comprising such a dominant negative allele. Each of these two groups shares a common feature, they require a dominant negative mismatch repair gene. However, the application does not provide written description support for any such repair gene alleles.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

In the present case, the Applicant has identified a number of genes associated with mismatch repair. The application has also identified two dominant negative alleles, each of a different mismatch repair gene. See e.g., page 27. However, these two species of known

dominant negative repair genes do not provide adequate support for the full scope of the claimed genus (i.e. they do not provide sufficient support for the genus comprising any dominant negative repair gene). Further, there is no description in the application of the structural or other features of any other dominant negative repair genes other than the general description that they are dominant negative repair genes, and may be found naturally or produced artificially. See e.g., page 11. In view of the limited number (two) of examples, and the lack of any identifying characteristic (other than the functional phenotypic trait) of the genus comprising dominant negative repair gene alleles, the Applicant has not provided either a sufficient number of working examples, or any other means of identifying genes (i.e. a common structural feature correlating with their status as dominant negative alleles) falling with the genus to provide adequate written descriptive support therefore.

6. **(New Rejection)** Claims 1, 14-25, 27, 38, 43, and 46-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for bacteria and methods of producing such, comprising one of the dominant negative alleles PMS2-134 or PMSR3, does not reasonably provide enablement for methods or bacteria involving any dominant negative repair gene allele. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI

1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, the factors deemed most relevant are the breadth of the claims, the amount of guidance and number of working examples, and the unpredictability of the art.

The claims have been described above. They are broadly drawn to methods or compositions involving any dominant negative mismatch repair gene. However, the application provides only two examples of such genes. However, although the application provides examples of other mismatch repair genes, the application provides no guidance in the modification of these genes into dominant negative alleles.

In contrast to the breadth of the claims, the art teaches that the modification of proteins (and thus of the genes encoding them) tend to be unpredictable absent guidance as to the relationship between the amino acids of the protein, and the protein's structure and functionality. See e.g., Bowie et al., Science 247: 1306-10. However, the present claims require not only the modification of the indicate genes so as to render the mismatch repair genes inoperative, but so as to make the inoperative genes the dominant allele. Because the art of protein, and gene, modification is unpredictable, in order for those in the art to be enabled for the making and use of negative alleles of the mismatch repair gene, they would first need to known what modifications to the gene would render it inoperative. In addition, to make the genes dominant,

those in the art would also have to know how to provide inoperative versions of the gene that are both inoperative in themselves, but are also able to interfere with the operative mismatch repair mechanism of the cells into which they are introduced.

Because neither the art nor the application provides any guidance as to how known mismatch repair genes may be modified to form dominant negative alleles, and in view of the presence of only two forms of such alleles, neither of which appears to share a common structure and thereby provide guidance in the manufacture of additional dominant negative alleles, the present application has not provided sufficient information to enable those in the art to practice the claimed inventions beyond those embodiments employing the two disclosed dominant negative alleles.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **(Prior Rejection- Reformed and Maintained)** Claims 1, 3, 15, 27, and 38, and 42 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Nicolaides 1 (U.S. Pre-Grant Publication 2002/0068284). The Applicant continues to argue that the reference does not teach or suggest the development of bacteria with resistance to multiple antibiotics. While the Examiner is not wholly persuaded by the arguments, the rejection has been reformed such

that the claims are now rejected over the teachings of Nicolaides 1, further in view of the teachings of Iris and Morris (cited in the prior actions).

The Morris reference has been previously described as suggesting motivation for the study of multiple-antibiotic resistant bacteria to improve the development of drugs against bacterial infections generally. See e.g., page 954. As previously described, the Iris reference teaches a method of identifying genes in microbes or other cells that confer on that cell a certain phenotype. Abstract, column 8, lines 11-32. Among the phenotypes for which the method is identified as useful in identifying is susceptibility or resistance to antibiotics. Column 9, lines 26-31. This reference also teaches that identification of such genes is useful in the development of strategies for disease control. Abstract, columns 1-2. Thus, this reference teaches that is beneficial to screen for cells expressing a particular phenotype, including antibiotic resistance in bacterium, such that the genes responsible for these phenotypes may be isolated and used to develop disease treatments. The combination of Morris and Iris would have suggested to those in the art the isolation and study of bacteria with multiple antibiotic resistance in the process of developing improved antibacterial drugs, and determining genes responsible for the development of such multiple resistances.

Because Nicolaides 1 teaches the use of the described mismatch repair deficient cells to generate cells with phenotypes of interest, and because the Morris and Iris references cumulatively suggest that a cell with a phenotype of interest would be a bacterial cell with multiple antibiotic resistance, it would have been obvious to those in the art to apply the teachings of Nicolaides 1 to generate multiple antibiotic resistance bacteria. The combined

teachings of the references therefore renders the claims obvious, and renders moot the Applicant's arguments with respect to the Nicolaides 1 reference alone.

9. **(Prior Rejection- Maintained)** In the prior action, claims 1, 19, 27, and 38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Iris (U.S. Patent 6,221,585) in view of Stemmer (U.S. Pub 2001/0049104) and Johnston (U.S. Patent 6,043,048), in view of Aronshtam et al. (Nucleic Acids Research, 24(13): 2498-2504), and further in view of the teachings of LeClerc (Science 274: 1208-11), Drummond (J Biol Chem, 271: 19645-48), and Moreland (Cancer Research, 59:2102-04), and Morris et al. (J Infect Dis 171: 954-60). The Applicant traverses the rejection generally by asserting that there is no motivation to combine the indicated reference, and that the references do not teach the introduction of a dominant negative allele of a mismatch repair gene. The Applicant also asserts that the references do not teach or suggest the re-stabilization of the hypermutable bacteria. This third argument in traversal applies only to the limitations of claim 27.

The Applicant presents four arguments in support the assertion that there is no motivation to combine the references. First, the Applicant asserts that the Johnson reference has been described as teaching the generation of multiantibiotic resistant bacteria through the culturing of cells in the presence of two or more antibiotics. It is noted that the action mailed in October 2003 stated that the reference teaches the generation of resistant bacteria by incubation in the presence of an antibiotic. While the term "identify" would be more appropriate that the term generate, it is also noted that the teachings of Johnson were not relied on alone. The action clearly aligns the identification technique of Johnson with the teachings of LeClerc, Drummond, Moreland, and

Morris, teaching that defective mismatch repair increases the occurrence of drug resistance, and of Morris and Iris, providing motivation to generate bacteria resistance to multiple antibiotics simultaneously. Thus, while the Applicant's argument that Johnston would not render obvious the generation of multiantibiotic resistant bacteria "simply by culturing them in medium containing two or more antibiotics" is accurate, this would be an obvious method of identifying bacteria with such characteristics wherein the resistance is induced by the introduction of a defective mismatch repair gene.

The Applicant next argues that the teachings of LeClerc, Drummond, Moreland, and Morris individually fail to teach or suggest the use of mismatch repair to induce genetic diversity or increased mutation. However, these references were not cited as making such a suggestion, but as supporting the assertion that those in the art would have had a reasonable expectation that introducing defective mismatch repair would be effective at generating bacterial cells with antibiotic resistant phenotypes. The actual suggestion for the introduction of a mismatch repair deficiency is found in the teachings of Stemmer, which both suggests and provides a motivation for the introduction of such a deficiency. The additional references targeted by the Applicant in the second argument merely provide two relevant teachings. First, they demonstrate that it was known in the art that mismatch repair deficiency would lead to the generation of desired phenotypes- including drug resistance. While the teachings of these references may be concerned with the prevention of such resistance, such teachings do not conflict with those of Iris or Stemmer. This is because the latter references are interested in the generation of resistant phenotypes, and identification of genes responsible therefore, for the purpose of developing strategies to overcome such mutation generated resistance. Thus, each of the references is

concerned with the development of treatments and strategies for avoiding drug resistance. While the totality of the teachings of the references must be considered, so must to totality of what is taught by all of the cited references. The fact that certain limitations are not taught by certain references does not defeat a rejection based on the combination of the deficient reference with other references providing the missing limitations, and where motivation to combine is present. Thus, the Applicant's arguments with respect to the deficiencies of these secondary references are not found persuasive.

The Applicant's third argument is concerned with the teachings of Stemmer. The Applicant asserts that the teachings of Stemmer teach away from the use of mismatch repair defects for the generation of new phenotypes for study. While the Applicant has cited portions of the reference that teach a weakness in methods (including mismatch repair deficiency) that induce random mutations throughout the genome, the Applicant fails to consider both 1) that the reference also teaches limitations of more site-directed methods (paragraph [0081], teaching that it is generally unpredictable what effect the mutation may have). Further, the reference also teaches that there are multiple means of generating mutations, each of which applications in the art. Included among the examples of such in mismatch repair. Paragraph [0119]. Thus, while the reference teaches a weakness of the method, in view of the further teachings, this is more a noted appreciation that each of the various methods of generating mutation has its strengths and weaknesses. Such is known in the art, and accepted, and does not constitute a teaching away. Rather, in view of the teachings of the other cited references, it would have been clear to those in the art that defective mismatch repair would be a useful method of inducing and identifying new mutations resulting in antibiotic resistance.

Finally, the Applicant returns to a previous argument describing the differences between the methodology of the Iris and Stemmer references. The Applicant argues that the teachings of the various references must be considered in their entirety, and that it is impermissible to pick and choose from any one reference only so much of it as will support a given position. While these remarks are clearly true, there applicability in the present case is not so clear. While certain teachings of Stemmer are looked to, the remaining teachings of the reference are not so much ignored as irrelevant. None of the other teachings teach away from the methodology of Iris, rather, as indicated above, the reference clearly recognizes the value of alternative technologies. Further, each of the Iris and Stemmer references are concerned with the same problem- that of identifying genotypes associated with target phenotypes. Thus, one of ordinary skill in that art would naturally have looked to the teachings of both references. While the methodologies of the two references vary, certain teachings of the references have common applicability to the problem at hand. In the present case, the teachings regarding the generation of diversity through artificial means so as to improve the ability to induce and identify the genetic causes of such diversity would clearly be generally applicable to the methodologies of both methods, and any other method in the field. Thus, although those in the art may not have been motivated to combine the particulars of the methods, certain teachings of the references, including those of generating diversity as suggested by Stemmer, would have a common applicability that those in the art would be motivated to introduce into alternative methodologies of dealing with the same problem. The Applicant's traversal on the basis of the differences between Stemmer and Iris are also, for the reasons above and of record, not found persuasive.

The Applicant's second asserted ground of traversal is that none of the references teach or suggest the modification of the bacterial cells with a dominant negative allele of a mismatch repair gene in order to induce hypermutability. In support of this argument, the Applicant sets forth a brief description of the teachings of each reference individually, and asserts that none of the reference teaches or suggests the claim limitation. This argument is not found persuasive. The rejection is based not on the teachings of any one reference but on the combination of the cited references. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Because the present rejection is based upon a combination of references as set forth in the prior actions, and in particular (with respect to the indicated limitation) on page 10 of the February 2003 Office Action. The argument in traversal is therefore not found persuasive.

The Applicant's third ground of traversal is that the rejection has not provided support for the assertion that the re-stabilization of the hypermutable bacteria would be obvious. While the Applicant may not have noted that the Examiner's assertion was a rational and scientific argument, the Applicant did note the assertion. Because the Applicant has not provided any arguments of evidence in contradiction of the assertion, and because the rejection was supported by a scientific rationale reasoned from knowledge generally available to those in the art the argument is not found persuasive and the rejection is maintained.

The rejection is therefore maintained for the reasons above, and the reasons of record.

10. **(Prior Rejection- Maintained)** Claims 1, 3, 27, 38, and 42 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Iris in view of Stemmer and Johnston as applied to claims 1, 2, 27, and 38 above, and further in view of either Nicolaides et al., Molecular and Cellular Biology, 18(3): 1635-1641 (Nicolaides 2) or Nicolaides et al., U.S. Patent 6,146,894 (Nicolaides 3) and of LeClerc, Drummond, Moreland, and Morris. The Applicant traverses this rejection on substantially the same grounds as presented above. For the reasons indicated above, the Applicant's traversal is not found persuasive. The rejection is therefore maintained.

11. **(Prior Rejection- Maintained)** Claims 1, 3, 14-25, 27, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of 1) Iris, Stemmer, Johnson, in view of Aronshtam; or 2) Iris, Stemmer, Johnston and either or Nicolaides 2 or 3, and in view of LeClerc, Drummond, Moreland, and Morris and further in view of Lin (U.S. Patent 6,025,400, column 1), Chang et al. (U.S. Patent 6,043,220, column 1), Setterstrom et al. (U.S. Patent 6,410,056, column 4), and The Merck Index, (1983, pages 2036, 5032-33, and 6448-449) as presented in the prior action. The rejection is extended to new claims 43, 45-47, which read on substantially identical subject matter; and to claims 48-50, which read on bacteria produced by the methods of the rejected method claims.

The Applicant traverses this rejection for the reasons described above, and on the grounds that no motivation has been provided for the combination of the additional references identifying known antibiotics with the other references suggesting the making of multiantibiotic resistant

bacteria. The previously described arguments are not found persuasive for the reasons also described above.

The Applicant's additional traversal on the basis of lack of motivation to combine the teachings of known antibiotics with the other references is also not found persuasive. In particular, the Applicant argues that resistance to each of the indicated antibiotics has not been established. This argument is not found persuasive. This is because the purpose of making such resistant bacteria is not solely to avoid known resistances, but to determine mechanisms that may result in antibiotic resistance in general so as to reduce or avoid overall development of resistance. See e.g., page 7 of the October 2003 Office action, and the teachings of Iris (abstract, columns 1-2), and Morris (esp., pages 954, left column, second paragraph). In view of this, those in the art would have been motivated to identify bacterial resistant to various combinations of antibiotics in order to identify as many possible routes of resistance as possible. Thus, regardless of whether the art has established resistance to the indicated antibiotics, those in the art would be motivated to identify causes of such resistance for the purpose of preventing their occurrence, and to develop improved antibiotics through identification of other targets for such compounds. The Applicant's argument is therefore not found persuasive.

12. **(New Rejection)** Claims 1, 3, 14-25, 27, 38, and 42-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicolaides 1 in view of Iris and Morris as applied against claims 1, 3, 15, 27, 38, and 42 above, and further in view of Stemmer, Lin, Chang, Setterstrom, and The Merck Index. The claims have been described above, as have the teachings of the various references. As indicated above, the teachings of Nicolaides 1 in view of Iris and

Morris render obvious the inventions of claims 1, 3, 15, 27, 38, and 42. The inventions of the additional claims vary only in the antibiotics against which resistance is induced. The additional teachings of Stemmer, Lin, Chang, Setterstrom, and The Merck Index both provide additional motivation for the making of multiantibiotic resistant bacteria (Stemmer), and demonstrate that the indicated compounds are known antibiotics. The motivation for the identification of bacteria resistant to such other compounds is the same as was provided above, and on page 7 of the October 2003 Office action. The combination of these references therefore renders the claimed invention obvious.

13. **(New Rejection)** Claims 27, 44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1) Iris, Stemmer, Johnson, in view of Aronshtam; or 2) Iris, Stemmer, Johnston and either or Nicolaides 2 or 3, and in view of LeClerc, Drummond, Moreland, and Morris, and further in view of Lin, Chang, Setterstrom, and The Merck Index as applied above, and further in view of Nicolaides 1. Claim 27 has been described above. Claim 46 reads on substantially similar subject matter. Claim 44 reads on a method of producing the multiantibiotic resistance bacteria wherein the dominant negative allele of the mismatch repair gene is PMSR3. With respect to claims 27 and 46, while the Examiner does not agree that the previously cited references fail to render these claims obvious for the reasons indicated with respect to claims 1, 19, 27, and 38 above, this rejection provides additional support for holding the claims obvious. The additional limitations of these claims are suggested by claims 58, 61, and 62, and by paragraph [0043] (page 5) of the Nicolaides 1 reference. The reference additionally provides both motivation and a reasonable expectation in the re-stabilization of the bacteria.

With respect to claim 44, the reference also teaches that the PMSR3 gene is a dominant negative allele of a mismatch repair gene, and is operative in bacterial cells. Pages 6-7. In view of these teachings, it would have been obvious to those in the art to use this allele in inducing hypermutability in bacterial cells in the methods suggested by the previously cited references. The motivation to do so, and the reasonable expectation of success are similar to those previously indicated with respect to the PMSR-134 gene in the February 2003 action.

The combined teachings of these references therefore render the claimed inventions obvious.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. **(New Rejection)** Claims 1, 3, 15, 27, 38, and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 16, 17, 71, and 73 of copending Application No. 09/780,675 in view of Iris and Morris. This rejection is on the same grounds as applied with respect to the publication based on this application (U.S. 2002/0068284) in view of Iris and Morris above. While the claims of the

application are generic to the present claims in that they do not require the additional limitations with respect to antibiotic resistance, such limitations would be obvious from the teachings of the application as described above with respect to the published version thereof, or over such teachings in view of Iris and Morris.

This is a provisional obviousness-type double patenting rejection.

16. **(New Rejection)** Claims 1, 3, 14-25, 27, 38, and 42-50 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims over claims 1, 16, 17, 71, and 73 of copending Application No. 09/780,675 in view of Iris and Morris as applied against claims 1, 3, 15, 27, 38, and 42 above, and further in view of Stemmer, Lin, Chang, Setterstrom, and The Merck Index. This rejection is on substantially the same grounds as indicated with respect to the rejection of the claims under 35 U.S.C. 103(a) over U.S. 2002/0068284 (the published version of the copending application) further in view of Iris, Morris, Stemmer, Lin, Chang, Setterstrom, and The Merck Index. While the claims of the application are generic to the present claims in that they do not require the additional limitations with respect to antibiotic resistance, such limitations would be obvious from the teachings of the application as described above with respect to the published version thereof, or over the indicated claims, in view of the additional references cited.

17. The above rejections are, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804 II(B)(1):

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 3/21/05